

REMARKS

The following remarks are submitted to be fully responsive to the final Official Action dated February 17, 2010. This response is thus timely submitted within the three-month shortened statutory period for response. Should any fees be required, the Commissioner is authorized to charge Kagan Binder Deposit Account No. 50-1775 and thereafter notify us of the same. Reconsideration of all outstanding grounds of the rejection and allowance of the subject application are believed in order and respectfully requested.

Claims 1-6, 8-14, 17, 32-37, and 39-43 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gifford, III et al. (US 5,695,504) and Hattler et al. (US 4,406,656). Withdrawal of this rejection is respectfully requested based upon at least the following.

In Applicants' previous response, independent claims 1 and 32 were amended to recite within the presently claimed methods, a step of advancing the tubular member distal region into the blood vessel lumen through the incision of the blood vessel or a blood vessel proximal end and then expanding the tubular wall and the lumen of the tubular member distal region radially outward within the blood vessel. Then, anastomosis can be performed by securing an end of a blood conduit to the vessel at the incision or vessel end while providing an oxygenated liquid flow from an outlet of the tubular member disposed within the conduit and into the blood vessel. As such, oxygenated liquid flows from the tubular member as its distal end and the lumen therein is expanded within the blood vessel. The Examiner acknowledges that the primary reference to Gifford III et al is deficient on this aspect. To reject claims 1 and 32, the Examiner thus further relies upon the reference to Hattler et al in combination with the disclosure of the Gifford III et al reference. Applicants submit that this attempted combination of disclosures of the Gifford III et al and Hattler et al references is unsupported and the withdrawal thereof is respectfully requested for at least the following reasons.

As shown in Fig. 54 of the Gifford III et al reference, balloons 694 and 695 are utilized for bridging a portion of the blood vessel at 682 and to permit blood flow through its internal lumen. Blood can also be provided through the lumen 699 of the catheter 691 as provided within a blood conduit that is to be connected to the side of the blood vessel 682 as an anastomosis site. The balloons 694 and 695 provide a blood flow bridge over a blockage site within the vessel 682 that includes a single lumen to permit blood flow over the blockage site from upstream of the blockage site and that can be supplemented from the catheter. As a result of the sealed volume

of the blood vessel between the balloons 694 and 695, the anastomosis can be performed in a blood free environment.

The devices of the Hattler et al reference are directed to those situations where multiple lumens are to be provided within a single catheter, where each lumen is designed for a volume to delivery solution within a blood vessel. In each case, a central lumen is provided of a set shape and as surrounded by other lumens that have an expandable portion for permitting fluid flow of a volume that is greater than that permitted by the collapsed lumen size. Devices of the Hattler et al reference solve a problem of delivering multiple fluids from a catheter that is easier to insert into a blood vessel through an insertion needle.

It is submitted that one of ordinary skill in the art would not even look to a device such as described in the Hattler et al reference for modifications relevant to the devices of the Gifford III et al reference as such are directed to completely different aspects of fluid delivery. Hattler et al does not describe its expandable portions as having anything to do with sealing or expanding to a blood vessel wall. The purpose is to permit greater fluid flow into the blood vessel. This is not the case with devices of the present invention or of the Gifford III et al reference. The balloons of devices of the Gifford III et al reference act to seal a portion of a blood vessel to create the blood free environment for anastomosis. The volume of the lumen is unaffected by inflation or deflation of the balloons. In the presently claimed invention, a delivery lumen is expanded to open against the blood vessel, but fluid flow is also unaffected as only the distal end of the tubular member expands.

Moreover, it is submitted that such a combination would not work. To provide expandable lumens to the device of the Gifford III et al reference would not operate to provide the bridge aspect of the device with inflated balloons. The T-shape lumen would not be able to expand in the way described in the Hattler et al reference. It simply wouldn't work. It is submitted that without the teachings of the subject disclosure, one of ordinary skill in the art would not have come up with the presently claimed invention based upon the disclosures of the Gifford III et al and Hattler et al references.

Applicants also point out the further distinguishing aspects as are recited within dependent claim 39. The Examiner has not provided any basis for rejecting the features of this claim. The Hattler et al reference does not disclose the provision of any type of flow restrictor that functionally works with a weakened wall portion of the device to cause a controlled expansion of the distal end portion.

Regarding independent claim 43, it is noted that claim 43 is now rejected after being indicated as containing the allowable subject matter from dependent claim 13. Claim 43 was submitted in Applicants' previous response in response to the indication of allowable subject matter within dependent claim 13. However, this claim is now rejected without any specific reasoning from the Examiner. Neither the Gifford III et al reference nor the Hattler et al reference disclose a withdrawing of a tubular member into blood conduit and further providing the oxygenated fluid through the tubular member to the lumen of the conduit proximal region as a step of an anastomosis procedure. It is submitted that claim 43 is also presently in condition for allowance.

Lastly, it is noted that claims 18-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gifford, II et al. and Hattler et al. as applied to claim 1 and further in view of Amor et al. (US 6,059,809). It is submitted that the Amor et al reference is deficient with respect to the insufficiencies of the Gifford III et al and Hattler reference as set out above. As such allowance of claims 18-20 along with claims 1-6, 8-14, 17, 32-37, and 39-43 is proper and respectfully requested.

Conclusion

Applicant submits that claims 1-6, 8-14, 17-20, 32-37 and 39-43 are currently in condition for allowance, a notice of which is earnestly solicited. If the Examiner finds any issue remaining after consideration of this response, the Examiner is invited to contact the undersigned, at the Examiner's convenience, in order to expedite any remaining prosecution.

Respectfully Submitted,

By:



Mark W. Binder, Reg. No. 32,642
Customer Number 77218
Phone: 651-275-9805
Facsimile: 651-351-2954

Dated: April 19, 2010